

LEGAL NOTICE NO. 271

REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister on the recommendation of the Drug Advisory Committee in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Regulations.

The Minister signifies his approval in respect of the following new drugs:

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bromhexine Hydrochloride Syrup 4 mg/5 ml	Sanpras Healthcare Pvt. Ltd. Plot No. 81, STICE, Musalgon, Tal.Sinnar, Nashik 422112, Maharashtra, India	India	Third Schedule
Lactulose Solution USP Oral Liquid 3.35 g/5 ml	do.	do.	do.
RIVAZEST Rivaroxaban Tablets 10 mg	Cipla Ltd. Plot No. 9 &10, Indore Special Economic Zone, Phase II, Pithampur, Dist. Dhar, Pin code 454775 Madhya Pradesh, India	do.	do.
RIVAZEST Rivaroxaban Tablets 15 mg	do.	do.	do.
RIVAZEST Rivaroxaban Tablets 20 mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
AVAFLO Tamsulosin 0.4 mg & Dutasteride 0.5 mg Capsules	PellTech Healthcare PvT. Ltd. Plot 20B, Tansa Farm Estate, Bhiwandi-Wada Road, Palghar, Maharashtra 421312, India	India	Third Schedule
Carboplatin Injection BP 450 mg/45 ml	TherDose Pharma Private Ltd Plot No.: 118,119 & 120, Sy.No.342, Road No 6, ALEAP Industrial Estate, Opp: JNTU, Pragathi Nagar, Gajularamaram, Medchal- Malkajgiri (Dist) - 500 090, Hyderabad, Telangana State, India	do.	do.
Carboplatin Injection BP 150 mg/15 ml	do.	do.	do.
SYNGESTO Dydrogesterone Tablets BP 10 mg	Emcure Pharmaceuticals Ltd Plot No. P1 and P2 I.T.B.T Park Phase - II, M.I.D.C Hinjawadi Pune 411057 Maharashtra State, India	do.	do.
Encicarb - Ferric Carboxymaltose Injection 50 mg/mL	Emcure Pharmaceuticals Ltd Survey No. - 2203/1, 2174, 2194, At & Post. – Dabhla, Visnagar – Gandhinagar Highway, Near Devda Patiya, Tal. - Vijapur, Dist. – Mehsana - 382 865 Gujarat State, India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
EMSULFAN (Busulfan Injection 60 mg/10 ml)	Emcure Pharmaceutical Limited Sm -14, 15 & 16 / 1, G.I.D.C., Sanand II, Charal, Tal. - Sanand, Dist. - Ahmedabad – 382 110, India	India	Third Schedule
MEBRAZ 1 mg/2 ml & 1.5 mg/3 ml (Eribulin Mesylate Injection 1 mg/2 ml & 1.5 mg/3 ml)	do.	do.	do.
NIMOVAR (Nimodipine Tablets BP 30 mg)	Gliesse Pharmaceuticals Private Limited Survey No. 23/3p & 24, Opp. Jeans Factory, Daduram Vistar, Village - Bagdol, Tal. - Kathlal, Dist. - Kheda - 387 630, Gujarat, India	do.	do.
Azaglin M (Dapagliflozin 5 mg and Metformin HCl 1000 mg Extended Release Tablets)	do.	do.	do.
Baraka Black Seed Oil Capsules 500 mg	Bio Extracts (Pvt) Ltd. 11A, Milepost Avenue, Colombo 3, Sri Lanka	Sri Lanka	Freely
NOW Probiotic- 10 Capsules	NOW Health Group Inc. 395 S. Glen Ellyn Rd., Bloomingtondale, Illinois, 60108, United States of America	United States of America	do.
NOW Super Enzymes Capsules	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
NOW High Potency Vitamin D-3 Softgels 5000 IU	NOW Health Group Inc. 395 S. Glen Ellyn Rd., Bloomington, Illinois, 60108, United States of America	United States of America	Third Schedule
NOW Glutathione 500 mg with Milk Thistle Extract & Alpha Lipoic Acid Capsules	do.	do.	Freely
NOW Liquid Chlorophyll Super Concentrated	do.	do.	do.
NOW Maca Capsules 500 mg	do.	do.	do.
NOW Omega-3 Fish Oil Softgels	do.	do.	do.
Louten T Sterile Ophthalmic Solution (Latanoprost 0.005% & Timolol 0.5%)	Poen Laboratories S.A.C.I.F.I., Bermudez 1004- (C 1407 BDR), Buenos Aires, Argentina	Argentina	Third Schedule
Alfa® Vitamins Vitamin C Gummies for Kids	Alfa Vitamins Laboratories, Inc. 4701 N.W. 77th Avenue Miami Florida 33166, United States of America	United States of America	Freely
Alfa® Vitamins Melatonin Gummies for Kids	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Alfa® Vitamins Melatonin Gummies Adults 5 mg (Black Berry Flavour)	Alfa Vitamins Laboratories, Inc. 4701 N.W. 77th Avenue Miami Florida 33166, United States of America	United States of America	Freely
Alfa® Vitamin Collagen C® Hydrolysate Peptides with Hyaluronic Acid Powder (Orange Flavour)	do.	do.	do.
Alfa® Vitamins Collagen C Hydrolysate with Biotin Capsules	do.	do.	do.
Alfa® Vitamins Collagen Gummies	do.	do.	do.
Alfa® Vitamins Vitamin E Softgels 1000 IU	do.	do.	do.
Alfa® Vitamins Vitamin C Chewable Tablets 1000 mg	do.	do.	do.
Alfa® Vitamins B Complex Formula Tablets	do.	do.	do.
Alfa® Vitamins Vitamin C Tablets 1000 mg	do.	do.	do.
Solaray Higher Absorption Magnesium Glycinate Veg Capsules 350 mg	Nutraceutical International Corporation. 550 W 2nd St BDO Building 2A, 2B, 2C Ogden, Utah, 84404., United States of America	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Solaray L – Arginine Veg Capsules 500 mg	Nutraceutical International Corporation. 550 W 2nd St BDO Building 2A,2B,2C Ogden, Utah, 84404., United States of America	United States of America	Freely
Solaray High Potency Vitamin D-3 Veg Capsules 250 mcg	do.	do.	Third Schedule
Solaray Vitamin D3 + K2 Veg Capsules 125 mcg/50 mcg	do.	do.	Freely
Solaray Zinc Veg Capsules 50 mg	do.	do.	do.
Solaray Timed Release Vitamin B-6 Veg Capsules 100 mg	do.	do.	do.
Solaray Vitamin B-Complex 100 Veg Capsules	do.	do.	do.
Solaray Timed Release Vitamin C with Rose Hips & Acerola Veg Capsules 1000 mg	do.	do.	do.
Solaray Once Daily Active Man Multivitamin Veg Capsules	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tiotropium Bromide Inhaler 9 mcg, 120 Metered Doses	Hetero Labs Limited, Unit-VII, Sy.No.50, Plot No.14, Phase-111 I.D.A, Jeedimetla Village, Quthbullapur Mandal, Medchal - Malkajgiri District, Pincode 500055, Telangana State, India	India	Third Schedule
Nicmel 150 (Nilotinib Capsules 150 mg)	Hetero Labs Limited Unit-V, Sy.No.439, 440,441 & 458 TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	do.	do.
Nicmel 200 (Nilotinib Capsules 200 mg)	do.	do.	do.
Cicacet 90 (Cinacalcet Tablets) 90 mg	do.	do.	do.
Cicacet 30 (Cinacalcet Tablets) 30 mg	do.	do.	do.
Cicacet 60 (Cinacalcet Tablets) 60 mg	do.	do.	do.
Ticagrelor Film Coated Tablets 90 mg	Annora Pharma Private Limited Sy. No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy District, Pincode- 501213, Telangana State, India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
JEMPERLI Concentrate for Solution for Infusion 500 mg/10 ml	Glaxo Operations UK Ltd (Trading as Glaxo Wellcome Operations) Harmire Road, Barnard Castle, County Durham, DL12 8DT, Durham, United Kingdom	United Kingdom	Third Schedule
Labetalol Hydrochloride Injection USP 100 mg/20 ml	Swiss Parenterals Ltd 808, 809, 810, Kerala Industrial Estate, GIDC, Nr. Bavla Dist. Ahmedabad 382 220, Gujarat, India	India	do.
Truxima Rituximab 100 mg/10 mL Concentrate for Solution for Infusion (Change of Marketing Authorization Holder)	Celltrion Inc. 20 Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea Marketing Authorization Holder: Celltrion Inc, Republic of Korea	Republic of Korea	do.
Truxima Rituximab 500 mg/50 mL Concentrate for Solution for Infusion (Change of Marketing Authorization Holder)	do.	do.	do.
Herzuma Trastuzumab 440 mg Powder for Concentrate for Solution for Infusion (Change of Marketing Authorization Holder)	do.	do.	do.
Remsima Infliximab Powder for Concentrate for Solution for Infusion 100 mg (Change of Marketing Authorization Holder)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Kalms Day Sugar Coated Tablets 26 mg (Change of Artwork; Addition of New Pack Sizes; Update of the Patient Information Leaflet)	G. R. Lane Health Products Limited Sisson Road, Gloucester GL20GR, United Kingdom	United Kingdom	Freely
Fastosil Lozenges Black Currant Flavour (Change of Brand Name; Change of Manufacturer; Change of Artwork Design)	Plethico Laboratories Pvt. Ltd. B-912. MIDC Road. Ratnagiri, Mirjole - 415639. District: Ratnagiri. Maharashtra, India	India	do.
Hyland's 4 Kids Night Time Cough and Mucus Syrup	Hyland's Consumer Health Inc 13301 South Main Street, Los Angeles, California, United States of America	United States of America	do.
Enflox W.S Enrofloxacin Veterinary Oral Powder 10%w/w	International Health Care Limited No. 40-9-60, GFD, Kohinoor Apartments, Kalanagar, Opp: Trust Hospital, Near Benz Circle, Vijayawada- 520 010, A.P-520010, India	India	Veterinary Use Only
Nature's Truth One Daily Essential Multivitamin Tablets	Nature's Truth LLC. Bohemia NY 11716, United States of America	United States of America	Freely
Nature's Truth Calcium Citrate 630 mg Plus D3 500 IU Coated Caplets	do.	do.	do.
Nature's Truth Testosterone Powerful Formula Softgels	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Greens Best Natto Capsules 500 mg	Greens Best 10651 N. Kendall Drive, Suite 118 Miami, Florida, United States of America	United States of America	Freely
Vivitra 150 (Trastuzumab 150 mg Lyophilized Powder for Intravenous Infusion Multi-Use Vial)	Zydus Lifesciences Limited Plot Survey No. 23, 25/P, 37, 40/P, 42-47, Sarkhej-Bavla N.H No. 8A, Opp. Ramdev Masala Village- Changodar, Tal - Sanand, District - Ahmedabad-382213, Gujarat State, India	India	Third Schedule
Vivitra 440 (Trastuzumab 440 mg Lyophilized Powder for Intravenous Infusion Multi-Use Vial)	do.	do.	do.
Bupialth (Bupivacaine Injection BP 5 mg/ml)	Livealth Biopharma PVT. Ltd Survey No. 494 - 495 Khambhat - Petload Rd, At & Post. Bamanva – 388 580, Tal. Khambhat Dist - Anand, Gujarat State, India	do.	do.
Hyrimoz 100 mg/ml Solution for Injection in a Prefilled Pen 40 mg/0.4 ml	Novartis Pharmaceutical Manufacturing GmbH Biochemiestraße 10, 6336 Langkampfen, Austria	Austria	do.
Hyrimoz 100 mg/ml Solution for Injection in a Prefilled Syringe 40 mg/0.4 ml	do.	do.	do.
Hyrimoz 100 mg/ml Solution for Injection in a Prefilled Pen 80 mg/0.8 ml	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Hyrimoz 100 mg/ml Solution for Injection in a Prefilled Syringe 80 mg/0.8 ml	Novartis Pharmaceutical Manufacturing GmbH Biochemiestraße 10, 6336 Langkampfen, Austria	Austria	Third Schedule
Olarbi Amlo 40 mg/10 mg Film Coated Tablets	Novartis Pharmaceutical Manufacturing LLC Verovskova Ulica 57, 1000 Ljubljana, Slovenia For: 1A Pharma GmbH, Germany	Slovenia	do.
Lectrum 22.5 mg Lyophilized Powder for Suspension for Injection	Eriochem S.A. Ruta 12, Km 452 (3107) Colonia Avellaneda, Departamento Paraná Entre Ríos, República Argentina	Argentina	do.
Erleada 240 mg Film-Coated Tablets	Catalent Pharma Solution LLC 1100 Enterprise Drive, Winchester, KY 40391, United States of America Packaged by: Janssen Cilag S.p.A. Via C. Janssen (loc. Borgo S. Michele) – 04100 Latina (LT), Italy	Italy	do.
Sandostatin® LAR® Powder and Solvent for Suspension for Injection 20 mg (Change in Name of the Manufacturer; Change in Name of the Primary Packager; Update in the Artworks to Reflect the Changes)	Novartis Pharmaceutical Manufacturing GmbH Biochemiestraße 10, 6336 Langkampfen, Austria Secondary Packager: Abbott Biologicals B.V. Veerweg 12, Olst, 8121 AA, Netherlands For: Novartis Pharma AG Basel, Switzerland	Netherlands	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Revolade Film-Coated Tablets 25 mg (Additional Manufacturer; Change in Country of Origin; Additional Primary and Secondary Packaging Site; Update of Label and Product Insert; Change of Shelf Life of Drug Product to 24 months)	Novartis Pharmaceutical Manufacturing LLC Verovskova Ulica 57, Ljubljana, 1000, Slovenia For: Novartis Pharma AG Basel, Switzerland	Slovenia	Third Schedule
Revolade Film-Coated Tablets 50 mg (Additional Manufacturer; Change in Country of Origin; Additional Primary and Secondary Packaging Site; Update of Label and Product Insert; Change of Shelf Life of Drug Product to 24 months)	do.	do.	do.
Paracetamol B. Braun Solution for Infusion 10 mg/ml (Additional Active Pharmaceutical Ingredient Manufacturer; Additional Excipient Manufacturer)	B. Braun Medical, S.A. Ctra. de Terrassa, 121 08191 Rubí (Barcelona), Spain	Spain	do.
FML Liquifilm Ophthalmic Suspension 0.10% (Additional Manufacturing Site)	Allergan Pharmaceuticals Ireland Unlimited Company Westport, Castlebar Road, Mayo, F28 AW83, Ireland Additional Manufacturing Site: AbbVie's Inc. Westport, Ireland	Ireland	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Darzalex Concentrate for Solution for Infusion 400 mg/20 ml (Additional Manufacturer of Drug Substance)	Cilag AG Hochstrasse 201, 8200 Schaffhausen, Switzerland For: Ethnor del Istmo S.A., Panama	Switzerland	Third Schedule
Sayana Suspension for Injection 104 mg/0.65 ml (Update of Manufacturing Site Address; Update of Secondary Artwork)	Pfizer Manufacturing Belgium NV Rijksweg 12 2870 Puurs-Sint-Amands, Belgium For: Pfizer S.A., Belgium	Belgium	do.
Sayana Suspension for Injection in a Pre Filled Syringe 104 mg/0.65 ml (Update of Manufacturing Site Address; Update of Primary and Secondary Artwork)	do.	do.	do.
Prevenar 13® Pneumococcal 13-Valent Conjugate Vaccine (Diphtheria CRM197 Protein) (Change in Secondary Packager's Address; Update of Secondary Artwork)	Pfizer Ireland Pharmaceuticals Grange Castle, Business Park, Clondalkin, Dublin 22, Ireland Secondary Packager: Pfizer Manufacturing Belgium NV Rijksweg 12 2870 Puurs-Sint-Amands, Belgium License Holder: Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgium For: Pfizer S.A., Belgium	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
NURTEC ODT 75 mg (Addition of Alternative Secondary Packaging Site)	Catalent UK Swindon Zydis Limited Frankland Road Blagrove, Swindon SN5 8RU, United Kingdom Alternative Secondary Packaging Site: Pfizer Ireland Pharmaceuticals Little Connell, Newbridge Co. Kildare, W12 HX57, Ireland	Ireland	Third Schedule
Xarelto Film Coated Tablets 2.5 mg (Addition of Alternative Manufacturing and Packaging Site; Update of Primary and Secondary Artwork)	Bayer Bitterfeld GmbH Ortsteil Greppin, Salegaster Chaussee 1 16803, Bitterfeld-Wolfen, Germany For: Bayer AG 51368 Leverkusen, Germany	Germany	do.
Kayexalate Powder for Oral and Rectal Suspension (Update of the Marketing Authorization Holder; Artwork Update; Logo Update)	Sanofi Winthrop Industrie 196 Rue Du Marechal Juin, Ammilly, 45200, France For: Sanofi Winthrop Industrie 82 Avenue Raspail, 94250 Gentilly, France	France	do.
Fasenra Solution for Injection in Pre-Filled Syringe 30 mg/1 mL (Additional Indication)	Manufactured and Primary Packaging (Prefilling) by: Catalent Indiana, LLC 1300 South Patterson Drive, Bloomington, IN 47403, United States of America Assembled and Packaged by: Resilience US, Inc. 8814 Trade Port Drive, West Chester, OH 45071, United States of America	United States of America	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Fasenra Solution for Injection in Pen 30 mg/1 mL (Additional Indication)	Manufactured and Primary Packaging (Prefilling) by: Catalent Indiana, LLC 1300 South Patterson Drive, Bloomington, IN 47403, United States of America Assembled and Packaged by: Resilience US, Inc. 8814 Trade Port Drive, West Chester, OH 45071, United States of America	United States of America	Third Schedule
Gardasil 9 Human Papillomavirus 9-valent Vaccine, Recombinant Suspension for Intramuscular Injection 0.5 ml Syringe (Update of Marketing Authorization Holder Name; Update of Manufacturer & Primary Packager Name; Update of the Artwork and Package Insert to Reflect the Changes)	Merck Sharp & Dohme LLC. 770 Sumneytown Pike, West Point, Pennsylvania 19486, United States of America Secondary Packager: Merck Sharp & Dohme BV Waarderweg 39, 2031 BN Haarlem, The Netherlands For: Merck Sharp & Dohme LLC. 126 East Lincoln Ave. P.O. Box 2000, Rahway, NJ 07065, United States of America	The Netherlands	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Symbicort Rapihaler 160/4.5 mcg (Change of Can Material from PFA to FEP/PES; Introduction of an Alternative Process for Purging Cans; Artwork Update)	AstraZeneca Dunkerque Production 224 Avenue De La Dordogne, Zone Ent Nord Gracht, Dunkerque, 59640, France For: AstraZeneca AG, Switzerland	France	Third Schedule
Xanax Tablets 0.5 mg (Update of License Holder; Update of Secondary Artwork)	Sanico N.V. Veedijk 59, Industriezone 4, 2300 Turnhout, Belgium Packaged by: Pfizer Italia S.r.l. Marino del Tronto, 63100 Ascoli Piceno (AP), Italy License Holder: Viatis Healthcare NV, Belgium	Italy	Controlled
Cialis Film-Coated Tablets 5 mg (Update of Primary and Secondary Artwork)	Lilly del Caribe, Inc. 12.6 KM 65th Infantry Road (PR1), Carolina, Puerto Rico (PR) Industrial Park, 00985, United States of America Packaged by: Lilly S.A. Avda. De la Industria 30, 28108 Alcobendas, Madrid, Spain For: Asofarma, S.A., Guatemala	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bondronat Concentrate for Solution for Infusion 6 mg (Addition of Secondary Packaging Site; Deletion of a Non-Significant Finished Product Specification Parameter)	Universal Farma, S.L. Calle del Tejido, 2, Azuqueca de Henares (Guadalajara), 19200, Spain For: Atmahs Pharma UK Limited Sovereign House, Miles Gray Road, Basildon, ESSEX, SS14 3 FR, United Kingdom	Spain	Third Schedule
Alecensa Hard Capsules 150 mg (New Indication)	Excella GmbH & Co.KG Nurnberger Strasse 12, 90537 Feucht, Germany Packaged by: Delpharm Milano S.r.l. Via Carnevale 1, 20054 Segrate Milano, Italy For: F. Hoffmann-La Roche Ltd. Grenzacherstrasse 124, 4058, Basel, Switzerland	Germany	do.
Epamin Solution for Injection 50 mg/mL (Change in Legal Entity Name; Update of Secondary Artwork)	Pfizer Manufacturing Belgium N.V. Belgium Rijksweg 12, 2870 Puurs-Sint-Amunds, Belgium License Holder: Viatrix Austria GmbH Guglgasse 15, 1110 Vienna, Austria	Belgium	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lyrica Capsules 300 mg (Change in Excipient Specifications and Finished Product Specifications)	Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1 79090 Freiburg, Germany For: Upjohn EESV Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, Netherlands	Germany	Third Schedule
Lyrica Capsules 150 mg (Change in Excipient Specifications and Finished Product Specifications)	do.	do.	do.
Lyrica Capsules 75 mg (Change in Excipient Specifications and Finished Product Specifications)	do.	do.	do.
Lyrica Capsules 25 mg (Change in Excipient Specifications and Finished Product Specifications)	do.	do.	do.
Panadol Rapid Film Coated Tablets 500 mg (Change of Primary Packaging Material; Change of Design of Primary and Secondary Packaging)	GlaxoSmithKline Dungarvan Ltd. Ireland Knockbrack, Dungarvan, Lisfennel Co. Waterford X35 RY76, Ireland Packaged by: GlaxoSmithKline Panama, S.A. Urbanizacion Industrial, Juan Diaz, A and B, Streets, Panama City, Panama	Panama	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Panadol Babies Solution 100 mg/ml (Change of the Legal Entity Name of the Holder; Change of Information on Primary and Secondary Packaging; Change of Logo from GSK to Hialeon; Update of Monograph and Insert)	Pharmetique S.A. Carrera 65B No. 13-13, Bogotá D.C., Colombia	Colombia	Freely
Panadol Children Syrup 160 mg/5 ml (Change of the Legal Entity Name of the Holder; Change of Information on Primary and Secondary Packaging; Change of Logo from GSK to Hialeon; Update of Monograph and Insert)	do.	do.	do.
Benjie's Sports Gel	V&S Pharmaceuticals Limited Lot 37 & 38 Frederick Settlement Industrial Park, Caroni, Trinidad and Tobago	Trinidad and Tobago	Freely
Jamieson Omega Complete Krill 500 mg Softgels	Jamieson Laboratories Ltd./ Nutricorp International 4025 Rhodes Drive, Windsor, Ontario, Canada	Canada	do.
Jamieson Milk Thistle Herbal Complex with Artichoke and Turmeric Caplets	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Misoprostol Tablets 200 mcg (Change of Artwork and Marketing Authorization Holder)	Apotex Inc. 150 Signet Drive Toronto, ON, M9L 1T9, Canada Packaged by: Apotex Inc. 4100 Weston Rd. Toronto, ON M9L 2Y6, Canada For: AA Pharma Inc. 1165 Creditstone Road, Unit #1. Vaughan, ON, L4K 4N7, Canada	Canada	Third Schedule
Vitamin B-12 5,000 mcg Fast Dissolve Tablets (Update of Artwork and Warnings for a More Regulated Control)	NATROL LLC 21411 Prairie Street, Chatsworth, California 91311, United States of America	United States of America	Freely
Melatonin 3 mg Fast Dissolve Tablets (Update of Artwork and Warnings for a More Regulated Control)	do.	do.	do.
Melatonin 5 mg Fast Dissolve Tablets (Update of Artwork and Warnings for a More Regulated Control)	do.	do.	do.
Novodia Soft Capsules	Ha Noi CPC1 Pharmaceutical Joint Stock Company Ha Binh Phuong Industrial Zone, Van Binh Commune, Thuong Tin District, Hanoi, Vietnam	Vietnam	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
FORTIFERRUM® + Oral Powder	Rioja Nature Pharma, S.L. C/Monte Perdiguero, 90 26500, Calahorra (La Rioja), Spain For: Aragonesa de Exportación Internacional 24 (AEI24) S.L. C/ Dr. Val Carreres Ortiz, nº2 50004 Zaragoza, Spain	Spain	Freely

Dated this 7th day of August, 2025.

L. BODOE
Minister of Health